



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-421F]

**Schedules of Controlled Substances: Temporary Placement of the Synthetic Cannabinoid
MAB-CHMINACA into Schedule I**

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic cannabinoid *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (common names, MAB-CHMINACA and ADB-CHMINACA), and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of this synthetic cannabinoid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research,

conduct instructional activities or chemical analysis, or possess), or propose to handle, MAB-CHMINACA.

DATES: This final order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the

United States, and the degree of dependence the drug or other substance may cause.

21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated her authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of the Administrator's intention to temporarily place a substance into schedule I of the CSA.¹

¹ As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA.

The Administrator transmitted the notice of intent to place *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (hereinafter referred to as MAB-CHMINACA) into schedule I on a temporary basis to the Assistant Secretary by letter dated May 14, 2015. The Assistant Secretary responded to this notice by letter dated June 3, 2015, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for MAB-CHMINACA. The Assistant Secretary also stated that the HHS had no objection to the temporary placement of MAB-CHMINACA into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments. MAB-CHMINACA is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for MAB-CHMINACA under section 505 of the FDCA. 21 U.S.C. 355. The DEA has found that the control of MAB-CHMINACA in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule MAB-CHMINACA was published in the *Federal Register* on September 16, 2015. 80 FR 55565.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C.

50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for MAB-CHMINACA, summarized below, indicate that this synthetic cannabinoid (SC) has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA 3-Factor analysis and the Assistant Secretary's June 3, 2015, letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under Docket Number DEA-421.²

Synthetic Cannabinoids

Synthetic cannabinoids (SCs) are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed SCs were first introduced into the designer drug market in several European countries as "herbal incense" before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008.

From 2009 to present, misuse of SCs has increased in the United States with law enforcement encounters describing plant material laced with SCs intended for human

² Although the published notice of intent stated that such items had been placed into the docket on [regulations.gov](http://www.regulations.gov), the Administration discovered in preparing this final order that they had in fact not been posted. However, those documents were available for review at the DEA. The DEA posted the cited analysis and letter to [regulations.gov](http://www.regulations.gov) upon discovery of the omission.

consumption. It has been demonstrated that the substances and the associated designer products are abused for their psychoactive properties. With many generations of SCs being encountered since 2009, MAB-CHMINACA is one of the latest, and based upon reports from public health sources and law enforcement, the misuse and abuse of this substance is negatively impacting the public health and communities.

The designer drug products laced with SCs, including MAB-CHMINACA, are often sold under the guise of “herbal incense” or “potpourri,” use various product names, and are routinely labeled “not for human consumption.” Additionally, these products are marketed as a “legal high” or “legal alternative to marijuana” and are readily available over the Internet, in head shops, and sold in convenience stores. There is an incorrect assumption that these products are safe, and that labeling these products as “not for human consumption” is a legal defense to criminal prosecution.

MAB-CHMINACA is an SC that has pharmacological effects similar to the schedule I hallucinogen THC and other temporarily and permanently controlled schedule I substances. MAB-CHMINACA has been shown to cause severe toxicity and adverse health effects following ingestion, including seizures, excited delirium, cardiotoxicity and death. With no approved medical use and limited safety or toxicological information, MAB-CHMINACA has emerged on the illicit drug market and is being abused for its psychoactive properties.

Factor 4. History and Current Pattern of Abuse

SCs were first encountered by CBP within the United States in November 2008. Since then, the popularity of SCs and their associated products has increased steadily as evidenced by law enforcement seizures, public health information, and media reports.

Despite multiple administrative and legislative actions to place SCs found on the illicit market into schedule I of the CSA, new generations of SCs intended to circumvent current law continue to be encountered with serious outcomes. Traffickers of these dangerous substances continue to attempt to skirt the law even after multiple control actions demonstrating a lack of regard for public health and safety. MAB-CHMINACA is an SC that was encountered following the hospitalization of 125 individuals around the Baton Rouge, Louisiana area in October 2014 (*see* factor 6 of the DEA 3-Factor). Since that time, multiple overdoses and deaths involving MAB-CHMINACA have been reported. For example, overdose clusters attributed to MAB-CHMINACA have been reported in Shreveport, Louisiana; Bryan, Texas; Beaumont, Texas; Hampton, Virginia; Hagerstown, Maryland; and multiple cities in the State of Mississippi (*see* factor 6 of the DEA 3-Factor). Specifically, in April 2015, the largest nationwide outbreak involving SCs was reported by multiple news outlets. In addition, State public health entities have collectively reported over 2,000 overdoses and at least 33 deaths across at least 11 States attributed to the misuse of SCs. Of these overdoses and deaths, currently available toxicology results have determined that a number of overdoses from this most recent cluster were connected to the ingestion of MAB-CHMINACA (*see* factor 6 of the DEA 3-Factor).

On April 29, 2015, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) reported multiple outbreaks of intoxications within the United States resulting from the ingestion of products believed to contain SCs. EMCDDA further reported that MAB-CHMINACA had been implicated in at least some of those cases.

EMCDDA also reported on two deaths involving MAB-CHMINACA, one in Hungary and the other in Japan.

A major concern, as reiterated by public health officials and medical professionals, remains the targeting and direct marketing of SCs and SC-containing products to adolescents and youth. This is supported by law enforcement encounters and reports from emergency departments; however, all age groups have been reported by the media as abusing these substances and related products. Individuals, including minors, are purchasing SCs from the Internet, gas stations, convenience stores, and head shops.

Smoking mixtures of these substances for the purpose of achieving intoxication have resulted in numerous emergency department visits and calls to poison control centers. As reported by the American Association of Poison Control Centers (AAPCC), adverse effects including severe agitation, anxiety, racing heartbeat, high blood pressure, nausea, vomiting, seizures, tremors, intense hallucinations, psychotic episodes, suicide, and other harmful thoughts and/or actions can occur following ingestion of SCs. Presentations at emergency departments directly linked to the abuse of MAB-CHMINACA have resulted in similar symptoms, including severe agitation, seizures and/or death (*see* factor 6 of DEA 3-Factor).

As discussed previously, it is believed most abusers of SCs or SC-related products smoke the product following application to plant material. Until recently, this was the preferred route of administration. Law enforcement has also begun to encounter new variations of SCs in liquid form. It is believed abusers have been applying the liquid to hookahs and “e-cigarettes,” which allow the user to administer a vaporized liquid that can be inhaled.

Factor 5. Scope, Duration and Significance of Abuse

Following multiple scheduling actions designed to safeguard the public from the adverse effects and safety issues associated with SCs, encounters by law enforcement and health care professionals indicate the continued abuse of these substances and their associated products. With each action to control SCs, illicit drug manufacturers and suppliers are adapting at an alarmingly quick pace to design new SCs in an attempt to circumvent regulatory controls. Even before DEA temporarily controlled the latest group of SCs, AB-CHMINACA, AB-PINACA, and THJ-2201, on January 30, 2015, MAB-CHMINACA was already available on the illicit market and responsible for overdoses and deaths (*see* factor 6 of DEA 3-Factor). From October 2014 to the present, multiple overdoses and deaths have been attributed to the abuse of MAB-CHMINACA.

On October 29, 2014, the State of Louisiana issued an emergency rule adding *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (MAB-CHMINACA) to the list of schedule I Controlled Dangerous Substances section of the Louisiana Administrative Code (LA. ADMIN. CODE tit. 46, § 2704 (2014)), upon the determination that it had a high potential for abuse and should be scheduled as a controlled substance to avoid an imminent peril to the public health, safety, and welfare.

Poison control centers continue to report the abuse of SCs and their associated products. These substances remain a threat to both the short- and long-term public health and safety. Exposures to SCs were first reported to the AAPCC in 2011. The most alarming report via the AAPCC was published on April 23, 2015. The AAPCC reported a dramatic spike in poison center exposure calls throughout the United States in 2015. The AAPCC reported 1,512 exposure calls in April 2015, representing an almost three-

fold increase in exposures to SCs as compared to the previous largest monthly tally (657 exposures in January 2012) since reporting began in 2011. It is likely that many of the calls are directly attributable to the abuse of MAB-CHMINACA based on its high prevalence in drug seizure reports and specimen test reports (*see* factor 6 and table 3 of DEA 3-Factor). Further, exposure calls to the AAPCC from within the first five months of 2015 (January 1 to June 1) are greater than the total exposure calls involving SCs from all of 2014. In addition, a majority of exposure incidents from 2011 to the present resulted in individuals seeking medical attention at health care facilities.

The following information regarding MAB-CHMINACA was obtained through NFLIS³ (queried on May 27, 2015):

MAB-CHMINACA: NFLIS—451 reports; first encountered in September 2014; locations include Arkansas, Indiana, Kansas, Louisiana, Missouri, Oklahoma, Texas, Virginia, and Wisconsin.

Factor 6. What, if Any, Risk There Is to the Public Health

MAB-CHMINACA was identified in a cluster of 125 subjects that presented to emergency facilities within the Baton Rouge and Shreveport, Louisiana areas in October 2014. On October 29, 2014, the Louisiana Secretary of the Department of Health and Hospitals announced the addition of MAB-CHMINACA into schedule I of the Controlled Dangerous Substances section of the Louisiana Administrative Code (LA. ADMIN. CODE tit. 46, § 2704 (2014)). From October 2014 to the present, multiple clusters of overdoses involving MAB-CHMINACA and at least four deaths attributed to the misuse and abuse of MAB-CHMINACA have been reported (*see* factor 6 and table 3 of the DEA 3-Factor).

³ National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

Adverse health effects reported from use of MAB-CHMINACA have included: seizures, coma, severe agitation, loss of motor control, loss of consciousness, difficulty breathing, altered mental status, and convulsions that in some cases resulted in death.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. The SCs encountered on the illicit drug market have no accepted medical use within the United States. Regardless, SC products continue to be easily available and abused by diverse populations. Unknown factors including detailed product analysis and dosage variations between various packages and batches present a significant danger to an abusing individual. Similar to previous SCs, MAB-CHMINACA has been found on plant material. Designer drug products have been found to vary in the amount and type of SC that plant material is laced with, which could be one explanation for the numerous emergency department admissions that have been connected to these substances.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety

Based on the data and information summarized above, the continued uncontrolled handling and abuse of MAB-CHMINACA poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for MAB-CHMINACA in the United States. A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I of the CSA. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for

use under medical supervision. Available data and information for MAB-CHMINACA indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated May 14, 2015, notified the Assistant Secretary of the DEA's intention to temporarily place this substance in schedule I. The Assistant Secretary responded to this notice by letter dated June 3, 2015, and stated that the HHS had no objection to the temporary placement of MAB-CHMINACA into schedule I. A notice of intent was subsequently published in the *Federal Register* on September 16, 2015. 80 FR 55565.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule MAB-CHMINACA into schedule I of the CSA, and finds that placement of this SC into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place this SC into schedule I of the CSA to avoid an imminent hazard to the public safety, the final order temporarily scheduling this substance will be effective on the date of publication in the *Federal Register*, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h) (1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done “on the record after opportunity for a hearing” conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, MAB-CHMINACA will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, MAB-CHMINACA must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles MAB-CHMINACA and is not registered with the DEA, must submit an application for registration and may not continue to handle MAB-CHMINACA as of [INSERT DATE

OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle MAB-CHMINACA, must surrender all quantities of currently held MAB-CHMINACA.

3. *Security.* MAB-CHMINACA is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of MAB-CHMINACA must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

5. *Quota.* Only registered manufacturers may manufacture MAB-CHMINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

6. *Inventory.* Every DEA registrant who possesses any quantity of MAB-CHMINACA on the effective date of this order, must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including MAB-CHMINACA) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records.* All DEA registrants must maintain records with respect to MAB-CHMINACA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle MAB-CHMINACA shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

8. *Reports.* All DEA registrants who manufacture or distribute MAB-CHMINACA must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Order Forms.* All DEA registrants who distribute MAB-CHMINACA must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

10. *Importation and Exportation.* All importation and exportation of MAB-CHMINACA must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in

accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

11. *Liability.* Any activity involving MAB-CHMINACA not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the *Federal Register* of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of 5 U.S.C. 553, as any further delays in the process for issuance of

temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action final order is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. 5 U.S.C. 808(2). It is in the public interest to schedule this substance immediately because it poses a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. The DEA

understands that the CSA frames temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to move quickly to place this substance into schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Amend § 1308.11 by adding paragraph (h)(25) to read as follows:

§ 1308.11 Schedule I

* * * *

(h) * *

(25) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers
(Other names: MAB-CHMINACA; ADB-CHMINACA).....(7032)

Dated: February 2, 2016

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-02302 Filed: 2/4/2016 8:45 am; Publication Date: 2/5/2016]